

### **REMARKS**

Claims 1, 2, 4-10, and 27-33 are pending in the application. Claims 1, 2, 4-10, and 27-33 were rejected in the Office Action. The Applicant has amended claims 1-2, 4-8, 9, and 27-33 as will be described below.

#### ***Claim Rejections - 35 U.S.C. § 112***

Claims 1, 2, 4-10, and 27-33 were rejected under 35 U.S.C. §112, second paragraph for being indefinite.

Claims 1, 8, 27, and 31 used the phrases "each opening", "at least one opening", and "at least one screw". The Office Action stated that each of these phrases lacked an antecedent basis. To correct all of these antecedent basis problems, the Applicant has universally removed the use of "at least one" and "each" before referring to the opening or the screw. Rather, the claims contain "an opening" and "a screw", which are subsequently referred to as "the opening" and "the screw". As "a" or "an" can include one or more of an object in a claim using the transitional phrase "comprising", this amendment does not affect the scope of the claims. See e.g.: KJC Corp. v. Kinetic Concepts Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000); Baldwin Graphic Systems Inc. v. Siebart, Docket No. 2007-1262, decided January 15, 2008, Fed. Cir. 2008.

Claims 4, 29, and 33 were rejected for reciting the limitation "the openings", as the Office Action stated that it was unclear whether "the openings" referred to the "at least one opening" or the "three openings". These claims have been amended such that "the openings" is now "the three openings" to the clearly recite the openings being referenced.

Claims 4, 29, and 33 each recited a limitation "the wall" which lacked antecedent basis. The claims have been amended such that "the wall" is now "the outer wall", which has proper antecedent basis.

Thus, the claim rejections under 35 U.S.C. § 112 have been overcome.

#### ***Claim Rejections - 35 U.S.C. § 101***

Claims 6, 7, 9, 10, and 27-33 were rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter. In particular, the Office Action states that claims 6, 9, 27, and 31 each recite, "prosthesis replaces a radial head", which positively recites a portion of the body. Per the suggestion of the Examiner, the Applicant has amended all instances of this phrase to recite, "prosthesis is adapted to replace a radial head". Thus, the rejection under 35 U.S.C. § 101 of claims 6, 7, 27, and 31, and all claims that depend therefrom, has been overcome.

#### ***Claim Rejections - 35 U.S.C. § 102***

Claims 1-2, 5-6, and 8-9 were rejected under 35 U.S.C. § 102(e) as being anticipated by Rauscher et al. (U.S. Pat No. 6,887,277) and claims 1, 2, 4-6, and 8-9 were rejected under 35 U.S.C. § 102(e) as being anticipated by Masini (U.S. Pat. No. 6,821,300). In the rejections under both Rauscher and Masini, the Office stated that the Applicant's claims do not require the head to be secured to the stem at the time at which the bone contacts the concavity. The Office Action indicated that if the Applicant were to claim "when the head of the prosthesis is secured to the stem" as recited in claims 27 and 31, that these rejections would be overcome.

Per the suggestion of the Examiner, the Applicant has amended independent claims 1 and 8 to include "when the head of the prosthesis is secured to the stem." The amended claim recites

a structure in which the outer wall of the head of the prosthesis includes a concave surface dimensioned to interface with another bone when the head of the prosthesis is connected to the stem.

Thus, the Applicant asserts that the rejections of claims 1-2, 4-6 and 8-9 under 35 U.S.C. § 102(e) have been overcome.

### ***Claim Rejections - 35 U.S.C. § 103***

Claim 4 was rejected under 35 U.S.C. § 103 (a) as being unpatentable over Rausher et al. As detailed above, amended claim 1 now recites a feature not shown or suggested in Rausher. Therefore, the rejection of claim 4 is overcome.

Claims 1, 2, 4-6, and 8-9 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Reiley (U.S. Pat. Pub. 2002/0055744). Claims 1 and 8 have been amended to further clarify that the structure of the modular prosthesis. The outer wall is dimensioned such that the head can be translated relative to the end of the stem in each of the directions referred to in the claims when the end portion of the stem is placed in the interior space of the head (as opposed to the previous claim language which stated "when the head is placed over the end portion of the stem"). Emphasis supplied. Reiley does not teach an interior space of a head that is translatable about a stem in the manner of the amended claims. Thus, the claims as amended present a limitation not found in Reiley and, thus, the rejection under 35 U.S.C. § 103(a) over Reiley has been overcome.

Claims 1, 2, 4-10, and 27-33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Martin (6,656,225). The Office states that Martin discloses all of the elements in the claims

except for the location and quantities of the screw connection(s), which the Office contends would be obvious. The Applicant disagrees.

First, with respect to the directions of movement of the head and the stem of the Applicant's claims, the Office Action states that:

Martin discloses. . . a stem (10), a head (30) having an outer wall (32) that can be placed over the end of the stem . . . the wall being dimensioned to be capable of movement in an axial direction and transverse direction relative to the stem axis (part 30 is capable of movement with respect to part 10-part 20 need not be present since the claims have the term "comprising", however even if part 20 is present, part 30 can move axially down on part 20 and rotationally, thus transversely) . . .

However, the amended claims require that the outer wall of the head be dimensioned such that (1) the head can be translated/moved in an *axial direction* in relation to the axis of the stem and the head can be translated in a *transverse direction* in relation to the axis of the stem as in claims 1 and 27 OR (2) the head can be translated/moved in a *first transverse direction* in relation to the axis of the stem and the head can be translated/moved in a *second transverse direction* in relation to the axis of the stem as in claims 8 and 31. In either case, the head must be capable of translating/moving in at least one, and sometimes two, transverse direction(s).

The Office states that if the part 20 is present, then part 30 can move axially down on part 20 and rotationally, thus transversely. However, rotational movement is not the same as transverse movement. According to Webster's Ninth New Collegiate Dictionary, rotate means "to turn about an axis or a center", whereas transverse means "set crosswise" or "made at right angles to the anterior-posterior axis of the body." Moreover, with respect to claims 1 and 8, none of the rotational movements described by the Office are not "translations".

More importantly, according to Martin (col. 6, lines 55-59), the outer shell 30 and the inner core 20 are rigidly fitted together (col. 6, lines 33-37) before the head is placed over stem component 10. Thus, any movement of the head relative to the stem in a direction other than

along the channel at which the head (20 and 30) and stem (10) connect is not disclosed by Martin.

With respect to the Office's statement that "[inner core] 20 need not to be present since the claims have the term 'comprising'", it is unclear to which claims are being referred to. In the case where the claims being referred to are the claims of Martin, an inner core 20 is, in fact, required (see claim 1, "...the head component comprises an outer shell and an inner shell"). The removal of part 20 from Martin changes the principle of operation of the reference and is impermissible under MPEP § 2143.02(VI). If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). In the case where the claims being referred to are the Applicant's claims, it is true that "part 20" is not required by the current claims. However, the fact that part 20 is not required by the Applicant's claims does not alter the teaching of the Martin, which requires that the part 20 slideably along a single direction engage the stem. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). MPEP § 2143.02(V).

For at least the above reasons, the Applicant believes that the rejections of claims 1, 2, 4-10, and 27-33 for being unpatentable under 35 U.S.C. § 103(a) have been overcome.

***Conclusion***

It is believed that the entire application is in a condition for allowance. The Office is authorized to charge a fee for a one month extension of time. This fee, and any other fees need, including further extensions of time, may be charged to Deposit Account 17-0055.

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Respectfully submitted,  
Scott P. Steinmann

By: 

Richard T. Roche  
Registration No. 38,599  
Quarles and Brady LLP  
411 East Wisconsin Ave.  
Milwaukee, WI 53202  
(414) 277-5805

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